TECO DIAGNOSTICS

K111206

1268 N. Lakeview Ave., Anaheim, CA 92807, U.S.A.
Phone: (714) 463-1111 Toll Free: 1-800-222-9880
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www.tecodiag.com

005 – 510(k) Summary

OCT - 4 2011

A. 510(k) Number:

B. Purpose for Submission:
New Device

C. Analyte:
Saliva Alcohol

D. Type of Test:
Semi-quantitative, chromogenic assay; visually read color change

E. Applicant:
Teco Diagnostics

F. Trade Name:
Teco Saliva Alcohol Test

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.3040, Alcohol Test System
2. Classification:
   Class II
3. Product code:
   DIC
4. Panel:
   Toxicology (91)

H. Intended Use:

2. Indication(s) for use:
   The Teco Saliva Alcohol Test is a semi-quantitative screening test for measuring alcohol in human saliva. This strip specifies the relative Blood Alcohol Concentration (BAC) at 0.0%, 0.02%, 0.04%, 0.08%, and 0.30% cut-off levels. Results can be used for the indication of alcohol intoxication. For in vitro diagnostic use only.
3. Special conditions for use statement(s):
   The assay is a disposable test for one-time use.
   The strip is for over-the-counter use.

I. Device Description:
The Teco Saliva Alcohol Test is used to detect the amount of alcohol in the saliva after consumption. This is a semi-quantitative test that is read visually. The test strip determines the relative Blood Alcohol Concentration at 5 cut-off levels (negative, 0.02%, 0.04%, 0.08% and 0.3%). The device consists of a test strip (1 test strip per foil pouch). The resultant color on the test strip is compared to the color blocks printed on the pouch.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Mission Saliva Alcohol Test; Acon Inc.

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2. Predicate 510(k) number(s):
   k093879
3. Comparison with predicate:

Trade Name	Teco Saliva Alcohol Test	ACON Mission Test
Manufacturer	Teco Diagnostics	ACON Labs
510(k) number	N/A	k093879
Intended use/indications for use	The Saliva Alcohol Test is a rapid screening test used for measuring alcohol in human saliva. Results are used in the diagnosis of alcohol intoxication.	Same
Methodology	Chromogenic	Same
Enzyme	Alcohol oxidase	Same
Sample Types	Saliva	Same
Measuring Units	Blood Alcohol Concentration (BAC%)	Same
Measuring Range	Negative 0.02% 0.04% 0.08% 0.30%	Same
Result	Semi-quantitative	Same
Read Time Window	2 minutes	2 to 3 minutes
Pad Methodology	Coupled enzymatic reactions using alcohol oxidase on ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB).	Same

K. Test Principle:

The Teco Saliva Alcohol Test is a plastic strip tipped with a reactive pad containing tetramethylbenzidine, alcohol oxidase, and peroxidase. The test is utilizes two coupled enzymatic reactions to create the visual changes in the presence of varying amounts of saliva alcohol. The first reaction consists of an oxidation reaction where the ethanol in the saliva is converted to aldehyde by the alcohol oxidase. The second reaction is the oxidation of TMB, the color indicator substrate, and is catalyzed by the enzyme peroxidase. The color change of the pad corresponds to the amount of present alcohol in the sample. The results are read by comparing the colored pad to the color chart found on the strip package

L. Clinical Performance Characteristics:

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Clinical study results indicate that the intended users were able to obtain comparable testing data when using the Teco Saliva Alcohol Test and the legally marketable ACON Mission Saliva Alcohol test.

M. Conclusion:

The performance characteristics of the Teco Saliva Alcohol Test were verified using method comparison, precision, linearity, shelf life, and stress studies. Testing results indicate that the Teco Saliva Alcohol Test compared with the ACON Mission Saliva Alcohol tests perform satisfactorily when used appropriately, as outlined in the package insert.

The clinical studies results demonstrate a substantial equivalency on performance between Teco Saliva Alcohol Test with predicate test, ACON Mission Alcohol Saliva test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

OCT 04 2011

Teco Diagnostics
c/o Mr. James Li
1268 N. Lakeview Avenue
Anaheim, CA 92807

Re: K111206
Trade Name: Teco Saliva Alcohol Test
Regulation Number: 21 CFR 862.3040
Regulation Name: Alcohol test system
Regulatory Class: Class II
Product Code: DIC
Dated: August 12, 2011
Received: August 17, 2011

Dear Mr. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k111206

Device Name: Teco Saliva Alcohol Test

Indications For Use:

The Teco Saliva Alcohol Test is a screening test for the semi-quantitative detection of the presence of ethyl alcohol in human saliva. The test strip indicates relative Blood Alcohol Concentrations (BAC) at 0.0%, 0.02%, 0.04%, 0.08%, and 0.30% cut-off levels. Results are used for the diagnosis of alcohol intoxication. The test is intended for both prescription and over-the-counter in vitro diagnostic use. The assay is a disposable test for one-time use.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use __X__. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111206